Veterinary Medicines Directorate

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Post Authorisation Assessments

Colombovac PMV

Vm 42058/4020

27 March 2025	Change in the specification parameter of the finished product to describe more accurately the appearance of the product.
16 November 2023	Addition of test for pH determination. Change of end of shelf-life specification for thiomersal content. Deletion of extraneous agents test on the finished product, based on assessment conducted in accordance Ph. Eur. 5.2.5. Update/harmonisation of the Part 2 dossier within current manufacturing practice in all countries.
19 August 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
11 January 2017	Change in the manufacturing process of the active substance.
02 October 2014	Change in a minor test procedure for this finished product. Deletion of a test procedure for the finished product. Replacement of a manufacturing site for the active substance. Replacement of a batch release site for the finished product. Replacement of a manufacturing site for the finished product.
12 December 2014	Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in the name of a manufacturer of the finished product. Deletion of a manufacturer of the finished product.
22 November 2013	Change in test procedure for the active substance.
16 July 2012	Change in test procedure performed on a starting material used in the manufacture of the active substance
19 December 2011	Changes to an existing pharmacovigilance system as described in the DDPS
02 September 2011	Addition of a site for secondary packaging and batch release
29 March 2011	Renewal
10 March 2011	Change of name of manufacturer of the active substance, blending, filling and assembly, quality control

	testing, labelling and batch release
16 June 2010	Change of MAH
15 December 2009	Change of method of manufacture of the active substance
27 June 2008	Harmonisation of SPC
28 May 2008	Change of legal category from NFA-VPS to POM-VPS
16 November 2006	Change of legal category from P to NFA-VPS Changes to the SPC and Product Literature to bring in line with new legislation